IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ORTHOPEDIC BONE SCREW PRODUCTS LIABILITY LITIGATION	:	MDL DOCKET NO. 1014
THIS DOCUMENT RELATES TO:	:	
RICHARD COSOM, MARGIE HALL, FRANCIS BURTON, STACIE RUEHLING and THE PLAINTIFFS LEGAL COMMITTEE	:	
v.	:	
THE UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.	:	C.A. No. 98-4643

MEMORANDUM AND PRETRIAL ORDER NO. 1813

BECHTLE, J. July 1, 1999

Presently before the court is defendants United States Food and Drug Administration's ("FDA"), Jane E. Henney's[1] and Donna E. Shalala's[2] motion to dismiss for lack of subject matter jurisdiction and plaintiffs Richard Cosom's, Margie Hall's, Francis Burton's, Stacy Ruehling's (collectively "Plaintiffs") and the Plaintiff Legal Committee's ("PLC") response thereto. For the reasons set forth below, said motion will be denied.

I. BACKGROUND

In August 1994, the Judicial Panel on Multidistrict

1. Since the filing of the Original Complaint, Jane Henney replaced Michael Friedman as the Lead Deputy Commissioner for the FDA. Pursuant to Federal Rule of Civil Procedure 25(d), Jane Henney, in her official capacity, has been substituted for Michael Friedman as a party defendant.

2. Donna Shalala is Secretary of the United States Department of Health and Human Services.

Litigation ("JPML") transferred all cases pending in federal courts against manufacturers of orthopedic bone screws to this court for coordinated pretrial purposes pursuant to 28 U.S.C. § 1407 as part of MDL No. 1014. Plaintiffs are individuals who have had pedicle screw fixation devices ("pedicle screw devices") implanted in the pedicles of their spines. In December 1994, the court appointed the PLC to direct the coordinated federal litigation on behalf of all plaintiffs in MDL No. 1014. In addition to pursuing primarily product liability claims against the manufacturers of the pedicle screws, Plaintiffs and the PLC filed the instant civil action challenging actions taken by the FDA relating to pedicle screw devices. Plaintiffs seek declaratory and injunctive relief pursuant to 28 U.S.C. § 2201 and 5 U.S.C. § 702.[3] Specifically, Plaintiffs request the court to issue a judgment and injunction:

> 1) declaring that the 1995 510K Clearance of the Danek TSRH system and the July 27, 1998 FDA classification of all pedicle screw fixation devices at Class II are contrary to law and are null and void;
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> 2) preventing the FDA from implementing or enforcing those actions; and
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> 3) directing the FDA to rescind all actions taken pursuant to the 1995 510K Clearance of the Danek TSRH system and the July 27, 1998 FDA classification of all pedicle screw fixation devices as Class II.

(Amend. Compl. ¶ 26.). Defendants filed this motion to dismiss

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3. The court has subject matter jurisdiction over this civil action pursuant to 28 U.S.C. § 1331.

under Federal Rule of Civil Procedure 12(b)(1). Defendants argue that Plaintiffs and the PLC lack standing to pursue this action. The court will review the applicable regulatory framework and the facts as alleged to determine whether Plaintiffs and the PLC have standing to pursue the action.

1. Regulatory Framework

The FDA regulates medical devices pursuant to the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, et seq. and the Medical Device Amendments ("MDAs"), 21 U.S.C. § 360, et seq. The FDCA and the MDAs are intended to regulate medical devices to allow the public to receive the benefits that medical research and experimentation provide while at the same time protecting the public from increasingly complex devices which pose serious risks if inadequately tested or improperly designed or used. S. Rep. No. 94-33, at 5 (1975), reprinted in 1976 U.S.C.C.A.N. 1070, 1075.

The FDA is required to classify all devices that were in commercial distribution prior to the effective date of the MDAs into one of three categories depending on the amount of regulation needed to provide reasonable assurance of their safety and effectiveness. 21 U.S.C. § 360c. Class I devices pose the least risk of harm to public health and safety, such as nonprescription sunglasses, tongue depressors, canes and elastic bandages. See 21 C.F.R. §§ 880.5075, 880.6230, 886.5850. Class II devices pose a greater risk to health, such as surgical sutures and unscented menstrual tampons, and are subject to

general and special controls. See 21 C.F.R. §§ 890.5570, 884.5470. Class III devices are the most heavily regulated. 21 U.S.C. § 360c(a)(1)(C). Devices that are intended to be used "in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health" or a device that "presents a potential unreasonable risk of illness or injury" fall into this category. 21 U.S.C. § 360c(a)(1)(C)(ii). A device introduced into interstate commerce after the effective date of the MDAs is automatically placed into Class III and requires "premarket approval"[4] before it can be lawfully marketed unless the FDA classifies or reclassifies the device by rulemaking into Class I or II. In addition to classification and reclassification, a device may be introduced into interstate commerce without premarket approval if the FDA issues an order finding the device to be "substantially equivalent" to a "predicate device" which was introduced into interstate commerce before enactment of the MDAs. 21 U.S.C. § 360c(i). This process is commonly referred to as a "510(k) Clearance."

2. Plaintiffs' Factual Allegations

Plaintiffs are individuals who, prior to January 1995, underwent surgery involving the implantation of a pedicle screw device. (Amend. Compl. ¶ 16.) On January 25, 1995, the FDA made

4. The premarket approval process includes rigorous scrutiny of a device's safety and efficacy through review and evaluation of laboratory testing and clinical data. 21 U.S.C. § 360e.

a determination that "when intended to provide immobilization and stabilization of spinal segments as an adjunct to spinal fusion in the treatment of Grades III or IV severe spondylolisthesis at the 5th lumbar - 1st sacral spine level, pedicle screw fixation devices were substantially equivalent to devices in commerce prior to [the effective date of the MDAs]."[5] (Amend. Compl. ¶ 22.) This determination allowed manufacturers to market pedicle screw devices for those limited uses. Id. Plaintiffs seek a judgment declaring this 510k Clearance null and void because they allege that it was obtained by the submission of fraudulent information. On July 27, 1998, the Department of Health and Human Services and the FDA published a final rule in the Federal Register with respect to the classification and reclassification of pedicle screw devices. (Amend. Compl. ¶ 170.) The final rule places all pedicle screw devices into Class II when intended to:

> provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion for the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fractures, dislocations, scoliosis, kyphosis, spinal tumors, and failed previous fusion (pseudarthrosis).

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5. Plaintiffs list May 28, 1996 as the effective date of the MDAs. (Amend. Compl. ¶ 22.) This date appears to be a typographical error. The effective date for the MDAs was May 28, 1976. Pub. L. 94-295.

(Amend. Compl. ¶ 171.)[6] Plaintiffs assert that this Classification/Reclassification final rule was promulgated in violation of federal law because Defendants acted in an arbitrary and capricious manner and acted without observing procedural requirements under the Administrative Procedures Act, 5 U.S.C. § 551, et seq., the FDCA and the MDAs. (Amend. Compl. ¶¶ 24, 171-213.) Plaintiffs allege, among other things, that the FDA promulgated the final rule without obtaining statutorily mandated scientific evidence to support the safety and efficacy of the pedicle screw devices. Plaintiffs seek judicial review of the FDA's final rule and ask the court to declare that it is invalid. Defendants argue that Plaintiffs lack standing to institute such an action.

II. LEGAL STANDARD

For the purposes of a motion to dismiss for lack of standing, the court must "accept as true all material allegations of the complaint and construe them in favor of the plaintiff." Trump Hotels & Casino Resorts, Inc. v. Mirage Resorts Inc., 140 F.3d 478, 483 (3d Cir. 1998) (citation omitted). The court will grant a motion to dismiss for lack of standing "only if, after accepting as true all of the facts alleged in the complaint, and drawing all reasonable inferences in the plaintiff's favor, no relief could be granted under any set of facts consistent with

6. The July 27, 1998 final rule is codified at 21 C.F.R. § 888.3070.

the allegations of the complaint." Id. Additionally, to demonstrate standing "[a]t the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice, for on a motion to dismiss we 'presum[e] that general allegations embrace those specific facts that are necessary to support the claim.'" Bennett v. Spear, 520 U.S. 154, 168 (1997) (citation omitted).

III. DISCUSSION

First, the court will discuss the doctrine of standing. Second, the court will determine if Plaintiffs have standing to challenge the FDA's July 27, 1998 final rule. Third, the court will determine whether the PLC has standing to challenge the FDA's July 27, 1998 final rule. Lastly, the court will determine whether Plaintiffs and the PLC must exhaust their administrative remedies before challenging the January 20, 1995 510K Clearance. Because, as discussed below, the court will allow the pending administrative review process to continue regarding the January 20, 1995 510K Clearance, the court will not address whether Plaintiffs' or the PLC have standing to challenge that 510K Clearance.

A. Standing

Article III of the United States Constitution requires that federal courts only entertain actual "cases or controversies." U.S. Const. art. III, § 2. The doctrine of standing is "an essential and unchanging part of the case-or-controversy

requirement of Article III." Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992). Article III constitutional standing contains three elements: (1) the plaintiff must have suffered an injury in fact; (2) there must be a causal connection between the injury and the conduct complained of; and (3) it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision. Trump Hotels, 140 F.3d at 484-85. Beyond these three requirements, the United States Supreme Court has set forth "a set of prudential principles that bear on the question of standing." Id. at 485 (citation omitted). One of those principles requires plaintiffs challenging the actions of federal agencies to demonstrate that they are within the "zone of interests" protected or regulated by the statute in question. Clarke v. Securities Indus. Ass'n, 479 U.S. 388, 395-96 (1987). In determining whether a plaintiff has standing under the zone of interests test, the court looks to "the particular provision of law upon which the plaintiff relies." Bennett, 520 U.S. at 175-76 (1997).

B. Standing of the Plaintiffs

1. Injury In Fact

To satisfy the first element of standing, Plaintiffs must allege an "injury in fact--an invasion of a legally protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical." Trump Hotels, 140 F.3d at 484. Plaintiffs argue that the FDA violated statutory requirements designed to protect the public from the

risks imposed by untested medical devices. Specifically, Plaintiffs allege, among other things, that the FDA: (1) failed to provide the public with relevant data and information to which it was legally entitled prior to promulgating its final rule; (2) failed to rely on well-controlled investigations as required to assess the efficacy of a medical device; and (3) failed to identify performance standards for pedicle screw devices. (Amend. Compl. ¶¶ 178-204.). Plaintiffs argue that the FDA's failure to comply with applicable statutory and regulatory requirements places them at an increased risk of exposure to an unsafe medical device. Plaintiffs further argue that because they suffer from conditions which sufficiently destabilized their spines to warrant the surgical implantation of a pedicle screw device, that they are now at risk of requiring additional surgeries, which would likely require reinstrumentation with a new or additional pedicle screw device. Plaintiffs' primary contention is that because the FDA promulgated its final rule in violation of statutory and regulatory requirements, they have been deprived of the information necessary to properly evaluate the risks and benefits of using the devices to treat the conditions from which they are suffering.[7] Defendants argue that

7. Plaintiffs also allege that the FDA's actions have "altered the legal regime" under which they are pursuing their product liability claims against the manufacturers of pedicle screw devices and will impair their rights in that litigation. The court finds that this alleged injury is too speculative to confer standing upon Plaintiffs. See Whitmore v. Arkansas, 495 U.S. 159, 159-60 (1990)(stating that litigants cannot prove in advance any particular result in their case); Lamoille Valley R.R. Co. v.

Plaintiffs' allegations are too speculative to satisfy the injury requirement.

The FDCA and the MDAs are, among other things, intended to protect American consumers from the risks of unsafe or ineffective medical devices. S. Rep. No. 94-33 (1975), reprinted in 1976 U.S.C.C.A.N. 1070. These statutes require an applicant seeking permission from the FDA to market a medical device to the public to demonstrate that the new medical device is safe and effective. Additionally, those statutes and accompanying regulations, require the FDA to take certain steps to properly evaluate the safety and effectiveness of a medical device before it grants permission to market the device. The district court in Stauber v. Shalala,[8] explained the general principles behind the statutory and regulatory framework of the FDCA as follows:

> Because the act places the responsibility on the sponsor of the drug to demonstrate the drug's safety and directs the FDA to approve for marketing only those drugs whose safety has been demonstrated, any significant uncertainty regarding the drug's safety is a burden to be borne by the sponsor, not the consumer. If the FDA has failed to follow the dictates of the act, as plaintiffs allege, it has shifted the costs of uncertainty from the sponsor of the drug to the American consumer. This increased risk of potential

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National Mediation Bd., 539 F. Supp. 237, 246 (D. Vt. 1982) (stating that standing cannot be predicated upon allegation that controversy has impeded settlement of other litigation "because, even if plaintiff were to prevail in the matter at bar, the effect of the relief requested upon the other litigation is highly speculative").

8. 895 F. Supp. 1178, 1187-88 (W.D. Wis. 1995) (finding that milk consumers had standing under FDCA to challenge FDA's approval of bovine growth hormone to be used in milk-producing cows).

> harm that the consumer must bear is an injury in fact for standing purposes.

Id. at 1187-88.

Here, Plaintiffs allege that the FDA failed to take the required steps necessary to properly evaluate the safety and effectiveness of pedicle screw devices before granting the manufacturers of those devices permission to market pedicle screw devices to the public. Plaintiffs argue that their injury is their exposure to a potentially dangerous medical device whose safety has not been demonstrated in accordance with the FDCA and MDAs. The court finds that Plaintiffs alleged injury satisfies the injury in fact element of constitutional standing. See Environmental Defense Fund, Inc. v. Hardin, 428 F.2d 1093, 1097 (D.C. Cir. 1970) (stating "Consumers of regulated products and services have standing to protect the public interest in the proper administration of a regulatory system enacted for their benefit.")(citations omitted); Stauber, 895 F. Supp. at 1187 (stating that "the FDCA creates legal rights or interests for consumers, the invasion of which creates standing even though no injury would exist without the statute."); Arent v. Shalala, 866 F. Supp. 6, 11-12 (D.D.C. 1994), aff'd in part, rev'd in part on other grounds, 70 F.3d 610 (D.C. Cir. 1995) (explaining that "the Administrative Procedure Act confers standing to a person aggrieved by agency action within the meaning of a relevant statute.") (citing Clarke, 479 U.S. at 394); Cutler v. Kennedy, 475 F. Supp. 838, 848-50 (D.D.C. 1979) (finding that increased

risk that consumers may be exposed to unsafe or ineffective drugs satisfies injury requirement to confer standing).

2. Causation

The court also finds that Plaintiffs allegations satisfy the causation element of standing. The causation requirement is satisfied where the injury is "fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court." Bennett v. Spear, 520 U.S. 154, 167 (1997). In order to satisfy the causation requirement, Plaintiffs need not prove a cause-and-effect relationship with absolute certainty. A "substantial likelihood of the alleged causality meets the test." Competitive Enter. Inst. v. National Highway Traffic Safety Admin., 901 F.2d 107, 113 (D.C. Cir. 1990) (citing Duke Power Co. v. Carolina Envtl. Study Group, 438 U.S. 59, 75 n.20 (1978)). Additionally, a "match between the statutory objective behind the agency regulation and the alleged injury can facilitate finding a causal link between the agency's conduct and the injury." Arent, 866 F. Supp. at 10-11 (citations omitted). As stated above, a statutory objective of the FDCA and the MDAs is to ensure that all medical devices approved for marketing to the public are safe and effective. If the FDA failed to take the required steps to properly evaluate the safety and effectiveness of pedicle screw devices then the statutory objectives were not met in this instance. The court finds that there is a substantial likelihood that Plaintiffs' alleged injury is fairly traceable to the

challenged action of the Defendants.

3. Redressability

The court also finds that Plaintiffs' allegations satisfy the redressability requirement. To satisfy the redressability requirement "it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." Lujan, 504 U.S. at 561 (citation omitted). Defendants argue that because physicians can make suggestions for an “off-label” use of a medical device to patients that Plaintiffs' alleged injury will not be redressed by the relief requested.[9] The court finds that a physician’s ability to suggest an off-label use for a medical device does not bar Plaintiffs from challenging the FDA’s alleged failure to comply with the FDCA, the MDAs and the regulations thereto. If Defendants' argument were followed to its logical extreme, then no consumer of a medical device could ever demonstrate standing to challenge the FDA’s compliance with statutory requirements designed to ensure the safety and effectiveness of regulated products. Such a result would frustrate the purpose behind these statutes which have been enacted, at least in part, to protect the public.[10] Here the alleged injury is Plaintiffs' increased

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9. See United States v. Algon Chem. Inc., 879 F.2d 1154 (3d Cir. 1989) (discussing relationship between FDCA and practice of medicine).

10. Additionally, Defendants argue that Plaintiffs may avoid the risk of injury by simply choosing not to undergo further surgery involving a pedicle screw device. Other courts have rejected this argument in the standing context. See Public Citizen v.

risk to pedicle screw devices that have not been subjected to required regulatory scrutiny. There is a substantial likelihood that the requested relief--a declaration that the FDA's final rule is arbitrary and capricious--if granted, would result in a ban on the lawful marketing of pedicle screw devices. Accordingly, Plaintiffs' alleged injury is capable of being redressed by the requested judicial review of the FDA's final rule.

4. Zone of Interests

Additionally, Plaintiffs' allegations satisfy the zone of interests test. Clearly the zone of interests sought to be protected by the FDCA and MDAs includes the interest of keeping the public safe from medical devices that have not been subjected to required procedures. See Cutler, 475 F. Supp. at 848 (describing FDCA as "a scheme whose principal beneficiaries are the nation's drug consumers"); see also Schering Corp. v. Food and Drug Admin., 51 F.3d 390, 395 (3d Cir. 1995) (stating that zone of interests test "is not so stringent that it requires the would-be plaintiff to be specifically targeted by Congress as a beneficiary of the statute"); Arent, 866 F. Supp. at 11 (stating

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Foreman, 631 F.2d 969, 974, n.12 (D.C. Cir. 1980) (finding that consumers had standing to challenge use of nitrites in bacon despite having choice of not eating bacon); Planned Parenthood Fed'n of America, Inc., v. Schweiker, 559 F. Supp. 658, 663-64 (D.D.C. 1983) (finding that class of unemancipated minors had standing to challenge regulations issued by Department of Health and Human Services limiting minors' access to family planning clinics despite having choice to abstain from sexual intercourse). This court rejects that argument as well.

that "the zone of interests adequate to sustain judicial review is particularly broad in suits to compel federal agency compliance with the law, since Congress itself has pared back traditional prudential limitations by the Administrative Procedure Act") (citation omitted). Accordingly, the court finds that Plaintiffs have standing to challenge the FDA's July 27, 1998 classification of pedicle screw fixation devices as Class II devices.

C. Standing of the PLC

In addition to the individual Plaintiffs, the PLC is also a named plaintiff in this civil action. The court created the PLC to represent and advance the interests of all plaintiffs in MDL No. 1014. Representational standing, where an organization brings suit on behalf of its members, "is established when 1) the members would have individual standing to sue; 2) the interests the organization seeks to protect are related to its goals; and 3) the claims do not require individual participation by the members." Natural Resources Defense Council v. Texaco Ref. and Mktg., Inc., 2 F.3d 493, 504-05 (3d Cir. 1993) (citation omitted). The first requirement is satisfied here. Because the court finds that the individual Plaintiffs in this case have standing, the court also finds that the persons represented by the PLC also have standing to sue. Those persons generally allege to have similar maladies that may require future surgery involving pedicle screw devices and, as potential

consumers of such devices, possess interests that the FDCA was designed to protect. The court also finds that the PLC satisfies the second requirement. In addition to certain administrative responsibilities, the crux of the authority given to the PLC by the court relates to coordinating and conducting all pretrial liability and damage discovery on behalf of all plaintiffs who filed civil actions that became part of MDL No. 1014. See MDL No. 1014, Pretrial Order No. 3, filed January 31, 1995. While challenging this final rule was not initially contemplated as a duty of the PLC under that Order, the court finds that the interests the PLC seeks to protect are interests "germane to the organization's purpose." Hunt v. Washington State Apple Adver. Comm'n, 432 U.S. 333, 343 (1977). Finally, the court finds that the claims presented here do not require the participation by individuals represented by the PLC. Accordingly, Defendants motion to dismiss the PLC on the ground that it lacks standing will be denied.

D. Exhaustion of Administrative Remedies

Defendants argue that Plaintiffs have failed to exhaust their administrative remedies with respect to their challenge of the FDA's January 20, 1995 510K Clearance of certain devices for use in the sacral area of the spine. On July 28, 1995, the PLC filed a Citizen Petition, pursuant to 21 C.F.R. § 10.30, challenging the validity of the January 20, 1995 510K Clearance. On September 28, 1998, the FDA informed the PLC that it was investigating the allegations contained in the Citizen Petition.

Defendants argue that because the FDA is investigating the allegations that judicial intervention at this time would be premature because it would interfere with ongoing agency proceedings.

Although the regulations to the FDCA offer an administrative remedy in the form of the Citizen Petition mechanism, the court is not required to compel the exhaustion of that remedy before undertaking judicial review. See Bracco Diagnostics, Inc. v. Shalala, 963 F. Supp. 20, 30 (D.D.C. 1997) (stating that "the Citizen Petition mechanism . . . is a creature of the FDA, not of Congress.") Because Congress has not required exhaustion under the applicable statutes, "sound judicial discretion governs" the question of whether to require exhaustion of remedies in this case. Id. (citation omitted).

In exercising its discretion the court must be mindful that "[t]he principle of exhaustion rests on the dual purposes of protecting administrative agency authority and promoting the economy of judicial resources." Id. (citations omitted). Applying those purposes to the instant case, the court will allow the Citizen Petition process to go forward. That investigation has been underway for a substantial period of time and the relief requested here may be granted through that process. Additionally, the court does not find that Plaintiffs will "suffer irreparable harm if unable to secure immediate judicial consideration of [its] claims." Id. (stating plaintiff need not await conclusion of administrative process if facing immediate

irreparable harm). The court will stay that portion of this civil action requesting relief relating to the January 20, 1995 510K Clearance for a reasonable time to allow the FDA to complete its investigation. However, because the FDA's investigation began approximately nine months ago, the court will require the FDA to submit a written report advising the court of the investigation's progress and an anticipated date of completion.

III. CONCLUSION

For the foregoing reasons, Defendants motion to dismiss for lack of standing will be denied.

An appropriate Order follows.

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v.	:	
THE UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.	:	C.A. No. 98-4643

PRETRIAL ORDER NO. 1813

AND NOW, TO WIT, this 1st day of July, 1999, upon consideration of defendants United States Food and Drug Administration's, Jane E. Henney's and Donna E. Shalala's motion to dismiss for lack of subject matter jurisdiction and plaintiffs Richard Cosom's, Margie Hall's, Francis Burton's, Stacy Ruehling's and the Plaintiff Legal Committee's response thereto, IT IS ORDERED that said motion is DENIED as follows:

(1) the motion is DENIED respecting Richard Cosom's, Margie Hall's, Francis Burton's, Stacy Ruehling's and the Plaintiff Legal Committee's ability to challenge the Food and Drug Administration's July 27, 1998 final rule;

(2) the motion is DENIED WITHOUT PREJUDICE respecting the January 20, 1995 510K Clearance pending the outcome of the Food and Drug Administration's investigation of the pending Citizen Petition filed on July 28, 1998; and

(3) the Food and Drug Administration SHALL file a written

report with the court within thirty (30) days from the date of this Order advising the court of the status of the Citizen Petition investigation and an anticipated date of completion for that investigation.

SO ORDERED.

LOUIS C. BECHTLE, J.